JAN 1 5 2004

510(k) SUMMARY FOR SOFT TISSUE FIXATOR

510k #: K 024185

Owner / Operator:	Future Medical Systems, SA.
Address:	265 Route de la Baronne, ST. Jeannet 06640 France
Phone:	011-33-4-92-12-32-56
Fax:	011-33-4-92-12-48-75
Contact:	Patrick Janin (US Native/ English speaker)

Official correspondent:

Company:	Future Medical Systems, Inc.
Address:	504 McCormick Drive, Glen Burnie, MD 21061
Phone:	410 761 9411 ext. 11
Fax:	410 760 9422
Contact:	Mr. Steve Janin

Date of submission: December 17th 2002

Name of device:

BIODHOC

Common name:

Soft tissue fixator

Classification:

MAI. Fastener, Fixation, Biodegradable, Soft tissue

Predicate device:

K991009: Biomet, Inc. RC Buttress.
K023963: FMS ADHOC CLAW.

Device intended use, description and substantial equivalence:

The BIODHOC is an implant used for rotator cuff repair in shoulder surgery. The BIODHOC is made of poly DL- lactic acid (PLLA) a bio absorbable polymer.

The BIODHOC and the predicate device have the same final function. In addition, the small differences in design do not affect the use, safety and effectiveness, between the device and the predicate device.

Based on these similarities and equivalences we believe our BIODHOC and the Biomet RC buttress (K991009) and the FMS ADHOC CLAW (K023963) are substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 1 5 2004

Future Medical Systems, SA
C/o Mr. Steve Janin
Future Medical Systems, Inc.
504 McCormick Drive
Glen Burnie, Maryland 21061

Re: K024185
Trade/Device Name: BIODHOC
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: II
Product Code: HTY
Dated: December 17, 2002
Received: October 20, 2003

Dear Mr. Janin:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Mark N Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510 K Number: K 024185

Device name: BIODHOC soft tissue fixator

INDICATIONS FOR USE:

The BIODHOC is an implant used for rotator cuff repair in shoulder surgery.

(Please do not write below this Line-Continue on another page if needed.)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use Yes (Per 21 CFR 801.109) OR Over-The-Counter-Use No (Optional Format 1)

for Mark N Milhern

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

K024185